

K253109 Reusable SPO2 Sensor (BSA307-47)Jan 7, 2026
105 days to decisionK253109 · Product code: **DQA** · Anesthesiology
Source: <https://www.510kdatabase.net/k253109/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter (DQA)
Date received	Sep 24, 2025
Decision date	Jan 7, 2026
Days to decision	105 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	BSA109-50; BSA109-310)

APPLICANT

Company	Shenzhen Best Electronics Co., Ltd.
Location	Shenzhen, CN
Contact	Martin Wong
510(k) history	2 submissions · 2 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	Shenzhen Joyantech Consulting Co., Ltd.
Contact	Lucy Yan

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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